



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0965]

Request for Nominations for Voting Members on a Public Advisory Committee; Pharmacy Compounding Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is requesting nominations for members to serve on the Pharmacy Compounding Advisory Committee (the Committee), Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research. The Committee provides advice on scientific, technical, and medical issues concerning human drug compounding under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

DATES: Nominations received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], will be given first consideration for membership on the Pharmacy Compounding Advisory Committee. Nominations received after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], will be considered for nominations to the Committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Nomination Portal:

<https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to

Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002; 301-796-9001, Fax: 301-847-8533, email: PCAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

FDA is requesting nominations for voting members on the Pharmacy Compounding Advisory Committee.

I. General Description of the Committee's Duties

The Committee provides advice on scientific, technical, and medical issues concerning human drug compounding under sections 503A and 503B of the FD&C Act (21 U.S.C 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

In implementing sections 503A and section 503B of the FD&C Act, the Agency may consult the Committee on: (1) drug products for inclusion on a list of drug products that have been withdrawn or removed from the market because such drug products or components of such

drug products have been found to be unsafe or not effective, and therefore cannot be compounded; (2) bulk drug substances for inclusion on lists of bulk drug substances that may be used in compounding; and (3) drug products for inclusion on a list of drug products that present demonstrable difficulties for compounding.

Meetings are held approximately one to two times a year, announced in the *Federal Register*, and are open to the public except as determined otherwise by the Commissioner or designee in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act (Pub. L. 92-463). Notice of all meetings shall be given to the public.

II. Criteria for Voting Members

The Committee consists of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the U.S. Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business

address and/or home address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Nomination Portal (see ADDRESSES). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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